UNITED STATES DISTRICT COURT FOR THE DISTRICT OF MASSACHUSETTS

IN RE COLUMBIA UNIVERSITY PATENT LITIGATION

MDL No. 1592 (MLW)

This Document Relates To All Actions

COLUMBIA UNIVERSITY'S MEMORANDUM OF LAW IN SUPPORT OF ITS MOTION TO STAY LITIGATION PENDING CONCLUSION OF REEXAMINATION AND REISSUE PROCEEDINGS IN THE PATENT AND TRADEMARK OFFICE

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I. PRELIMINARY STATEMENT

In the wake of a recent decision by the Patent and Trademark Office ("PTO") granting a third party's request for reexamination of the patent at the core of this multidistrict litigation, Columbia asks this Court to stay all proceedings in these lawsuits pending the outcome of reexamination. Because the validity and enforceability of Columbia's patent, United States Patent No. 6,455,275 ("275 patent"), lies at the heart of each of these actions, a stay is necessary to promote efficiency while the PTO considers virtually all of the issues currently before this Court.

The reexamination proceeding will directly address the central allegation in these six consolidated actions: whether the '275 patent is invalid for double-patenting in view of three earlier patents awarded to Columbia arising from the same scientific research. The PTO should be allowed to render its expert judgment on the validity of this patent before the parties and this Court expend the substantial time and resources that will be required to navigate discovery, claim construction, motion practice, and trial. This is particularly true given that the PTO can allow Columbia to narrow the claims of the '275 patent during the reexamination procedure to overcome the double-patenting challenge. It would make little sense for the parties to spend millions of dollars litigating the validity of patent claims that the PTO may amend or cancel during the reexamination procedure.

Moreover, the PTO's review of the '275 patent will not be limited to assessing just the double-patenting challenge. Rather, the PTO will undertake a comprehensive review of most every other challenge raised by plaintiffs to the validity and enforceability of the '275 patent. This is because Columbia intends to invoke a related PTO procedure called "reissue" that allows Columbia to request the PTO to either broaden or narrow the claims of the '275 patent. The reissue procedure requires the PTO to reconsider the validity of the

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'275 patent to the fullest extent—just as it would upon original examination of a patent application. Accordingly, given the potential of reexamination and reissue to result in substantial changes to the '275 patent—whether by amendment to or cancellation of one or more claims of the patent—a stay is appropriate to allow the PTO to determine the validity and scope of the patent's claims prior to extensive litigation in this Court.

Allowing the PTO to apply its specialized expertise prior to litigation has the potential to simplify the issues dramatically. During the stay, the PTO will have the opportunity to determine the proper scope (and number) of claims in the '275 patent and to express its expert views on the fundamental issues at stake in these cases. Accordingly, a stay at this stage will allow for a fresh start of these actions based on whatever claims of the '275 patent emerge from the PTO. Without a stay, the parties will engage in duplicative litigation of the very issues that the PTO will consider during the reexamination and reissue proceedings.

Moreover, a stay of these actions poses no threat of prejudice to plaintiffs. None of the cases has progressed in any meaningful way beyond the pleading stage. Other than some very limited discovery (all of it produced by Columbia) and the exchange of some initial disclosures, there has been no activity in any of these actions. There is no scheduling order entered or trial date set. Indeed, it is the *absence* of a stay that poses a real threat of prejudice to plaintiffs, for if these actions proceed apace, plaintiffs will unnecessarily risk exposure to any counterclaims that Columbia may assert for infringement of the '275 patent. To conserve judicial resources and avoid wasteful duplication of effort, Columbia respectfully requests that the Court enter a stay of this action until the conclusion of proceedings before the PTO.

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II. SUMMARY OF FACTS

Events Precipitating This Motion To Stay Α.

This multidistrict litigation consists of six actions, all of which involve the validity and enforceability of the '275 patent. Five of the actions were filed by large pharmaceutical companies seeking a declaration that the '275 patent is invalid and/or unenforceable. The sixth action was filed by Columbia against Johnson & Johnson (which subsequently filed its own action against Columbia). Each plaintiff in the five actions against Columbia entered into an agreement with Columbia granting a license to a bundle of patent rights, including the '275 patent, in exchange for the payment of royalties. All plaintiffs have failed to pay the required royalties under their license agreements for products covered by the '275 Accordingly, with one exception, Columbia has terminated plaintiffs' license agreements.

The central allegation in each lawsuit is that the '275 patent is invalid because of double patenting—i.e., the claims of the '275 patent are the same as, or obvious variants of, U.S. Patent Nos. 4,399,216, 4,634,665, and 5,179,017 (the "Original Axel Patents"), three earlier patents issued to Columbia based on the same original patent application as the '275 patent. All of the lawsuits also allege that the '275 patent is invalid or unenforceable based on theories of inequitable conduct and prosecution laches.² All but one of the actions include allegations that the '275 patent is invalid based on 35 U.S.C. §§ 101, 102, 103, and

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¹ See Immunex Compl. ¶¶ 66-67; Biogen Compl. ¶41; Genentech Compl. ¶¶ 49-50; Johnson & Johnson Compl. ¶ 37; Wyeth Compl. ¶¶ 25-26.

See Immunex Compl. ¶¶ 71-73, 77-79; Biogen Compl. ¶¶ 48, 45; Genentech Compl. ¶¶ 60-64, 54-56; Johnson & Johnson Compl. ¶¶ 45, 41-43; Wyeth Compl. ¶¶ 37, 31-34.

112, which set forth the basic requirements for patentability.³ Except for some limited discovery provided by Columbia, and the exchange of initial disclosures in some cases, none of the cases has progressed past the pleading stage. Gindler Decl. ¶ 2.⁴

On February 25, 2004, the Public Patent Foundation filed a petition with the PTO requesting reexamination of the '275 patent pursuant to 35 U.S.C. § 302. Gindler Decl. Ex. A. The Public Patent Foundation describes itself on its website (www.pubpat.org) as "a not-for-profit legal services organization working to protect the public from the harms caused by the patent system." The petition alleges that a "substantial new question of patentability raised by this request is whether each of the claims 1 to 20 of [the '275 patent] is unpatentable for double patenting" in view of the Original Axel Patents. These very same double-patenting challenges are at the heart of each lawsuit in this multidistrict litigation.

On May 10, 2004, the PTO notified Columbia that it had accepted the petition for reexamination and that it will consider whether the '275 patent is invalid for double patenting in view of the Original Axel Patents. Gindler Decl. Ex. B. In the immediate future, Columbia intends to file an application for reissue of the '275 patent and a request that the PTO merge the reexamination and reissue proceedings. Reexamination and reissue proceedings are public and in the merged proceedings plaintiffs will have an opportunity to file papers with the PTO expressing their views on all matters at issue.

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³ See Immunex Compl. ¶¶ 66, 68; Biogen Compl. ¶ 42; Johnson & Johnson Compl. ¶ 38; Wyeth Compl. ¶ 27.

⁴ The accompanying Declaration of David I. Gindler contains the exhibits cited in this Memorandum.

B. Reexamination And Reissue Procedures

1. Reexamination

"Any person at any time may file a request for reexamination by the [PTO] of any claim of a patent on the basis of any prior art. . . ." 35 U.S.C. § 302. The PTO may grant the request for reexamination if the cited prior art raises a "substantial new question of patentability" with respect to the subject patent. 35 U.S.C. § 303.

Once the PTO grants a petition for reexamination, the process of reexamination is "conducted according to the procedures established for initial examination under" 35 U.S.C. §§ 132-33. 35 U.S.C. § 305. This means that the PTO will review the '275 patent using the same procedures that apply to a new patent application, except that the PTO will only consider the validity of claims of the '275 patent on the basis of prior art. 37 C.F.R. § 1.552. As part of the reexamination process, "the patent owner will be permitted to propose any amendment to his patent and a new claim or claims thereto, in order to distinguish the invention as claimed from the prior art cited . . . , or in response to a decision adverse to the patentability of a claim of a patent." 35 U.S.C. § 305. Following reexamination, and after the time for appeal has expired, the PTO will publish "a certificate canceling any claim of the patent finally determined to be unpatentable, confirming any claim of the patent determined to be patentable, and incorporating in the patent any proposed amended or new claim determined to be patentable." 35 U.S.C. § 307(a).

Unlike the typical patent prosecution proceeding, which is conducted on an *ex parte* basis without public involvement, a reexamination proceeding is open to the public. MPEP

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The grant of a reexamination petition is not a substantive decision that a patent is invalid, nor is it a conclusion that a *prima facie* case of invalidity exists. Manual of Patent Examining Procedure § 2240, at 2200-39 (8th ed., Feb. 2003 Rev.) ("MPEP"). Instead, it is simply a decision that the petition presents a substantial new question of patentability.

§ 2209, at 2200-15; MPEP § 2232, at 2200-31. Accordingly, plaintiffs can monitor all events that occur during reexamination. Moreover, in certain circumstances, plaintiffs can make their own written submission to the PTO explaining the reasons that they contend that the '275 patent is invalid on prior art grounds. 37 C.F.R. §§ 1.550(g), 1.535.

2. Reissue

Under 35 U.S.C. § 251, a patent holder may submit a reissue application "[w]henever any patent is, through error without any deceptive intention, deemed wholly or party inoperative or invalid, by reason of a defective specification or drawing, or by reason of the patentee claiming more or less than he had a right to claim in the patent..." An "error" that justifies reissue can include a patent attorney's "failure to appreciate the full scope of the invention." *Mentor Corp. v. Coloplast, Inc.*, 998 F.2d 992, 995 (Fed Cir. 1993). Because it is common for a patent holder to seek reissue when the PTO has granted a request for reexamination, PTO procedure permits the merging of the reissue application and the reexamination petition into a single proceeding. 37 C.F.R. § 1.565(d).

Reissue involves a broader analysis than reexamination. In a reissue proceeding, the PTO can reconsider the validity of the subject patent on any ground that can be considered during the original examination of a patent application; in a reexamination proceeding, the PTO can only reconsider the validity of the subject patent in light of prior art. 37 C.F.R. §§ 1.176, 1.552. Moreover, in a reissue proceeding, the patent holder can seek to broaden or narrow the patent claims as appropriate for the scope of the invention; in a reexamination proceeding, the patent holder can only seek to narrow the patent claims to overcome the cited prior art. 35 U.S.C. § 251; 37 C.F.R. § 1.552(b). At the conclusion of reissue proceedings where the patent is found to be valid, the PTO "shall, on the surrender of such

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part of the term of the original patent." 35 U.S.C. § 251.

Reissue proceedings allow plaintiffs to play an active role in the review of the '275 patent. The file of a reissue proceeding is open to the public. MPEP §§ 1430, at 1400-37. Plaintiffs will thus have complete access to all of Columbia's submissions and all of the PTO's office actions. In addition, PTO procedure allows plaintiffs to submit arguments and evidence to the PTO explaining their contentions that Columbia is not entitled to the '275 patent. MPEP §§ 1441.01, 1901-1920; 37 C.F.R. § 1.291.

III. ARGUMENT

A. Courts Apply A Liberal Policy In Favor Of Granting Motions to Stay Litigation Pending Resolution Of Reexamination Or Reissue Proceedings, Particularly When The Stay Is Requested At An Early Stage Of The Litigation

"Congress enacted the reexamination procedure to provide an inexpensive, expedient means of determining patent validity which, if available and practical, should be deferred to by the courts." *Digital Magnetic Systems, Inc. v. Amsley*, 213 U.S.P.Q. (BNA) 290, 290 (W.D. Okla. 1982). In light of this legislative intent, the courts have developed "a liberal policy in favor of granting motions to stay proceedings pending the outcome of USPTO reexamination or reissuance proceedings." *ASCII Corp. v. STD Entertainment USA, Inc.*, 844 F. Supp. 1378, 1381 (N.D. Cal. 1994). This is a wise policy, for in the absence of a stay, "the court may waste time examining the validity of claims which are modified or eliminated altogether during reexamination." *Guthy-Renker Fitness, LLC v. Icon Health and Fitness Inc.*, 48 U.S.P.Q.2d (BNA) 1058, 1060 (C.D. Cal. 1998). This potential waste of judicial resources is not simply a theoretical matter: Approximately three-fourths of reexamined patents are either amended or invalidated by the PTO. *Tap Pharmaceutical Products, Inc. v. Atrix Laboratories, Inc.*, No. 03 C 7822, 2004 WL 422697, *2 (N.D. Ill.

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March 3, 2004) ('the PTO invalidates 10% of the patents it reexamines and amends the claims in 64%.").

In addition to conserving judicial resources, a stay pending reexamination provides a number of other important benefits, including utilization of "the PTO's particular expertise in evaluating the prior art." Alloc, Inc. v. Unilin Decor N.V., No. Civ. A 03-253-GMS, 2003 WL 21640372, *2 (D. Del. July 11, 2003). This expertise can play an important role in cases such as this one that involve complex technical issues. GPAC, Inc. v. D.W.W. Enterprises, Inc., 144 F.R.D. 60, 63 (D.N.J. 1992) ("The Court is equally impressed that the PTO may be in a better position to evaluate the validity of the '111 patent especially in view of the prior art references. The requisite technical acumen is better represented in the PTO."). Moreover, reexamination ordinarily serves to clarify or narrow the issues in dispute and streamline the litigation. "If the reexamination proceeding invalidates or narrows a claim or claims, the issues at trial will be simplified. Similarly, if the reexamination proceeding reaffirms all the claims as issued, the Court will then have the benefit of the PTO's expert analysis of the prior art that allegedly invalidates or limits the claims." Softview Computer Products Corp. v. Haworth, Inc., 56 U.S.P.Q.2d (BNA) 1633, 1636 (S.D.N.Y. 2000); see also Alloc, 2003 WL 21640372, at *2 ("it is beyond dispute that the court would benefit from the narrowing of the numerous complex issues relating to claims, which, if clearly defined, would streamline discovery and subsequent litigation.").

Given the obvious benefits of a stay pending the conclusion of reexamination or reissue proceedings, courts "have uniformly granted and upheld stays" where sought before extensive discovery has been conducted or a trial date has been set. *Clintec Nutrition Co. v. Abbott Laboratories*, No. 94 C 3152, 1995 WL 228988, *3 (N.D. Ill. April 14, 1995). A review of the cases reveals that, "[m]ost often, a request for a stay has been denied due to

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the late stage of the litigation, the fact that discovery was or would be completed, or trial had been set." *Perricone v. Unimed Nutritional Services, Inc.*, No. Civ.A.301CV512(CFD), 2002 WL 31075868, *3 (D. Conn. July 18, 2002). On the other hand, "in cases such as that before this Court which have not progressed beyond the initial litigation stages . . . the reexamination procedure should be utilized." *Digital Magnetic Systems*, 213 U.S.P.Q. at 290.

B. This Court Should Exercise Its Discretion To Stay This Multidistrict Litigation Until The Conclusion Of Reexamination And Reissue Proceedings

In determining whether to grant a stay of litigation pending the conclusion of reexamination or reissue proceedings, courts have looked to three factors. One factor requires the court to decide "whether a stay will simplify the issues in question and trial of the case." *Softview*, 56 U.S.P.Q.2d at 1635-36. Another important consideration is "whether discovery is complete and whether a trial date has been set." *Id.* Finally, the court should look to "whether a stay would unduly prejudice or present a clear tactical disadvantage to the non-moving party." *Id.* All of these factors strongly favor granting a stay of these six consolidated actions.

1. A Stay Will Permit The PTO To Simplify The Underlying Issues In These Actions

Because the process of reexamination often covers the same issues that are before a court in a patent validity action, this first factor in the stay analysis is rooted in basic logic: Where reexamination or reissue may streamline or even eliminate the central issues before the Court, there is no sense in litigating the same matters prior to a decision by the PTO. *See Gould v. Control Laser Corp.*, 705 F.2d 1340, 1342 (Fed. Cir. 1983) (the "purpose of the reexamination procedure is to eliminate trial of that issue (when the claim is canceled) or to facilitate trial of that issue by providing the district court with the expert view of the PTO

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(when a claim survives the reexamination proceeding)"). This factor strongly supports the granting of a stay.

The meaning of the claims in the '275 patent will be a fundamental issue in this case. Plaintiffs' double-patenting allegations turn on the interpretation of the patent claims. Eli Lilly & Co. v. Barr Labs., Inc., 251 F.3d 955, 968 (Fed. Cir. 2001) ("Generally, an obviousness-type double patenting analysis entails two steps. First, as a matter of law, a court construes the claim[s]..."). The same is true of plaintiffs' allegations that the '275 patent is invalid under 35 U.S.C. §§ 101, 102, 103, and 112. Akami Techs., Inc. v. Cable & Wireless Internet Servs., Inc., 344 F.3d 1186, 1192 (Fed. Cir. 2003) ('The first step in any invalidity analysis is claim construction..."). Similarly, Amgen's claim for a declaration of non-infringement, as well as any counterclaims that Columbia may assert for infringement of the '275 patent, also turn upon the interpretation of the '275 patent. Cybor Corp. v. FAS Techs., Inc., 138 F.3d 1448, 1454 (Fed. Cir. 1998) ("An infringement analysis involves two steps. First, the court determines the scope and meaning of the patent claims asserted . . . "). Given that claim interpretation will play a central role in this litigation, it makes no sense to proceed with these six related actions when it is entirely possible that some or all of the claims of the '275 patent may be amended as a result of reexamination or reissue. E.g., Vitronics Corp. v. Conceptronic, Inc., 36 F. Supp. 2d 440, 442 (D.N.H. 1997) ("The reexamination process could more precisely define the scope of claim 1, or it could leave claim 1 unchanged. Because determining the scope of the disputed claim is central to

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See also AK Steel Corp. v. Sollac and Ugine, 344 F.3d 1234, 1241 (Fed. Cir. 2003) ("an enablement [35 U.S.C. § 112 validity] inquiry typically begins with a construction of the claims"); Helifix Ltd. v. Blok-Lok, Ltd., 208 F.3d 1339, 1346 (Fed. Cir. 2000) ("The first step of an anticipation analysis is claim construction."); In re Goodman, 11 F.3d 1046, 1052 (Fed. Cir. 1993) (35 U.S.C. § 101 double-patenting "hinges upon the scope of the claims in question. If the claimed inventions are identical in scope, the proper rejection is under 35 U.S.C. § 101 . . .") (internal citation omitted).

the resolution of this case, it would be inefficient for the court to expend time and resources engaging in claim construction while the scope of the claim is under review at the PTO.").

Moreover, while Columbia has every confidence that the PTO will reaffirm the validity of the '275 patent during the reexamination and reissue proceedings, Columbia recognizes that the PTO has the authority to invalidate the entire patent and reject any proposed amendments to the claims. It would be a tremendous waste of time and effort for the parties and the Court to continue the litigation of this action, only to have the PTO invalidate the entire patent at the end of the day. See Softview, 56 U.S.P.Q.2d at 1636 ("if the parties continue to litigate the validity of the claims in this Court, and the PTO subsequently finds that some or all of the claims at issue here are invalid, the Court will have wasted time and the parties will have spent additional funds addressing an invalid claim or claims."); Tap Pharmaceutical, 2004 WL 422697, at *2 ("There is a significant chance that the PTO will either invalidate this patent or drastically reduce its scope. This creates a very real possibility that the parties will waste their resources litigating over issues that will ultimately be rendered moot by the PTO's findings.").

In addition to allowing the PTO to eliminate or clarify key issues and the reby avoid a waste of judicial resources, a stay will give the PTO an opportunity to render its expert opinion on the validity and enforceability issues at the center of this multidistrict litigation. Here, in its notice granting the petition for reexamination, the PTO expressly agreed to address plaintiffs' core invalidity contention—that the claims of the '275 patent are obvious variants of the claims of the Original Axel Patents. Gindler Decl. Ex. B. In addition, the PTO will also address plaintiffs' invalidity challenges to the '275 patent under 35 U.S.C. §§ 101, 102, 103, and 112 because, in a reissue proceeding, the PTO must examine the '275 patent in the same manner as an original application. 37 C.F.R. §1.176 ("A reissue

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application will be examined in the same manner as a non-reissue, non-provisional application, and will be subject to all the requirements of the rules related to non-reissue applications."). Moreover, the reissue proceeding also provides an opportunity for the PTO to address plaintiffs' arguments that the '275 patent is unenforceable because of prosecution laches. *See In re Bogese II*, 303 F.3d 1362, 1369 (Fed. Cir. 2002) (holding that "the PTO has authority to order forfeiture of rights for unreasonable delay").

The reexamination will also allow the PTO to offer guidance relevant to plaintiffs' allegations that Columbia committed inequitable conduct during the prosecution of the '275 patent by failing to disclose certain material prior art references. Columbia intends to inform the PTO of the references that plaintiffs contend should have been disclosed, thereby allowing the PTO to consider whether any of the references on which plaintiffs base their inequitable conduct allegations impact the validity of the '275 patent. Although the PTO will not determine during the reexamination or reissue proceedings whether Columbia committed inequitable conduct in the course of the original prosecution of the '275 patent, MPEP §§ 1448, 2258, at 2200-67, the PTO's treatment of plaintiffs' prior art references will provide the Court with a neutral expert assessment of what the references disclose and how they relate to the claims of the '275 patent—information that is highly relevant to the question of whether the prior art references were material, one of the critical elements that plaintiffs must prove to establish inequitable conduct. See Clintec, 1995 WL 228988, at *6 ("[s]ince prior art will necessarily be considered by the PTO during the reexamination process in evaluating the reissue application (not in terms of inequitable conduct but as a

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⁷ During prosecution of a patent application, the PTO is required to consider invalidity based on 35 U.S.C. §§ 101, 102, 103 and 112. MPEP §§ 706.02 (examination of 35 U.S.C. §§ 102, 103); 706.03(a), (c)-(d) (examination of 35 U.S.C. §§ 101, 112); Chapter 2100.

matter of determining the validity of Clintec's claims), it would seem to make sense to stay Abbott's claim for inequitable conduct which relies heavily on allegations regarding prior art.").

Plaintiffs may argue that their complaints assert certain claims for relief that will not be considered by the PTO, such as their claim that the '275 patent is unenforceable because of patent misuse⁸ or that Columbia violated its obligations to the National Institute of Health by obtaining and asserting the '275 patent.9 Yet most of these claims for relief (which in any event are at the periphery of this multidistrict litigation) depend at least in part upon plaintiffs' allegation that the '275 patent is invalid and unenforceable. Accordingly, while the PTO may not analyze the merits of these particular claims for relief, the PTO will render an expert opinion on the validity and enforceability issues on which these claims are based. 10

If plaintiffs have any concerns that, during the reexamination and reissue proceedings, the PTO might not focus on some aspect of their allegations regarding the

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See Immunex Compl. ¶¶ 82-83; Johnson & Johnson Compl. ¶¶ 78-81; Wyeth Compl. ¶¶ 80-84.

See Immunex Compl. ¶¶ 89-92; Wyeth Compl. ¶¶ 87-98.

¹⁰ To the extent that these claims for relief turn on legal or factual issues that are separate from the validity or enforceability of the '275 patent, courts have consistently held that it is improper to proceed with discovery in a piecemeal fashion when the PTO is reviewing the patent at the center of the litigation. See Thomas & Betts Corp. v. Tishman Research Corp., No. 86 Civ. 1926 (MJL), 1986 WL 13455, *2 (S.D.N.Y. Nov. 17, 1986) (rejecting plaintiffs' argument that "its claims of patent misuse and fraudulent patent procurement will not be addressed by the PTO" during reexamination and therefore discovery should proceed on those claims, court held that "[w]e see no reason for piecemeal discovery on a few claims at a time."); Clintec, 1995 WL 228988, at *6 (denying motion to stay only select claims pending reexamination and reissue proceedings because "proceeding on one claim and not the other would be grossly unfair. It is unfair and inconvenient to bifurcate cases or discovery where overlapping issues exist."); Pacesetter Inc. v. Cardiac Pacemakers, Inc., No. Civ. 02-1337(DWF/SRN), 2003 WL 23303473, *1 (D. Minn. Nov. 19, 2003) ("respectfully reject[ing] the option of a partial stay of the two patents that are not in reexamination" because "duplicity and overlap will occur when addressing issues such as experts, discovery, damages, and products").

validity and enforceability of the '275 patent, plaintiffs can monitor the proceedings (which are public) and submit protests to the PTO explaining the reasons that they contend the '275 patent should be revoked in its entirety. MPEP §§ 1430; 1441.01; 1901.02. In short, whether on its own accord or with prodding from the plaintiffs, the PTO will have an opportunity to consider and opine on virtually every major issue in this multidistrict litigation concerning the validity and enforceability of the '275 patent. Armed with the expert view of the PTO on the central issues in these lawsuits, this Court and the parties will be better able to litigate any remaining issues following reexamination. E.I. Du Pont de Nemours & Co. v. Cetus Corp., No. C-89-2860 MHP, 1990 U.S. Dist. LEXIS 18414, *10 (N.D. Cal. Dec. 3, 1990) ("The court therefore regards the PTO's reexamination findings of validity for all claims . . . as highly probative on the issues considered and with respect to the prior art considered during reexamination. It thus views plaintiff's burden of proving invalidity as heavier than it would have been in the absence of the reexamination.") (citations omitted); see also Custom Accessories, Inc. v. Jeffrey-Allan Indus., Inc., 807 F.2d 955, 961 (Fed. Cir. 1986) (reversing a district court's judgment of invalidity because, inter alia, the district court failed "to give any credence to the PTO reexamination proceeding, which upheld the validity of [the relevant] claims").

2. Given That All Six Actions Are In Their Earliest Stages, A Stay Is Warranted

Another important consideration on a motion to stay pending reexamination or reissue is the relative progression of the litigation itself. Softview, 56 U.S.P.Q.2d at 1635-36. Where discovery has not yet begun in earnest and where no trial date has been set, a motion to stay should be granted because the PTO's conclusion is likely to shape the future of the still largely undeveloped litigation. See Alloc, 2003 WL 21640372, at *3 (granting stay in part because "discovery in this case has not yet begun, nor has a discovery schedule

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been entered at this time"); Guthy-Renker, 48 U.S.P.Q.2d at 1060 (holding that the "relevant factors weigh heavily in favor of staying the proceedings pending the conclusion of the reexamination" because, among other things, "this case is in its incipient stages" and "[t]he parties have not engaged in extensive discovery and no trial date has been set"). Even where the litigation has progressed significantly, it is not uncommon for a court to grant a stay to avoid the waste of conducting a trial while the PTO considers the validity of the patent at the heart of the litigation. See, e.g., Loffland Bros. Co. v. Mid-Western Energy Corp., No. Civ. 83-2255-E, 1985 WL 1483, *2 (W.D. Okla. Jan. 3, 1985) (granting stay after considerable discovery, pre-trial conference, and trial date set).

Plaintiffs cannot dispute that very little discovery has occurred in any of these actions. Other than Columbia's substantive responses to a single set of interrogatories and requests for admission, Columbia's production of a small set of documents, and some initial disclosures, there has been no substantive discovery in any of these cases. Gindler Decl. ¶ 2. In fact, as multidistrict transfer was only recently granted, there is not yet any formal discovery plan or scheduling order in these actions. Thus, like the first factor, this second factor in the stay analysis firmly supports granting this motion to stay all actions until the PTO has rendered a decision on the reexamination of the '275 patent.

3. Plaintiffs Will Not Suffer Any Prejudice Or Clear Tactical Disadvantage From A Stay

The final consideration in deciding a motion to stay pending reexamination or reissue is whether the non-moving party would suffer prejudice or a clear tactical disadvantage if the stay were granted. Softview, 56 U.S.P.Q.2d at 1635-36. As discussed below, plaintiffs in this multidistrict litigation face no such risk.

A stay will not increase plaintiffs' financial exposure in these lawsuits. As permitted under Lear, Inc. v. Adkins, 395 U.S. 653 (1969), plaintiffs have stopped paying royalties to

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Columbia while challenging the validity of the '275 patent. *Id.* at 673 ("federal policies would be significantly frustrated if licensees could be required to continue to pay royalties during the time they are challenging patent validity in the courts."). Accordingly, if plaintiffs prevail in the litigation, the date of judgment is irrelevant because they will owe no royalties to Columbia from the date on which they filed their respective actions (assuming they stopped paying royalties under the '275 patent by that date). On the other hand, if Columbia prevails in the litigation, the date of judgment is irrelevant because the '275 patent will remain in force until 2019.

Nor will a stay create a clear tactical disadvantage for plaintiffs. Quite to the contrary, a stay may limit plaintiffs' exposure in connection with any counterclaims for infringement of the '275 patent that Columbia may assert. In particular, a stay at this stage would protect plaintiffs from the possibility that Columbia will secure a judgment of patent infringement and an award of damages for which plaintiffs would be liable even if the PTO later determined that the '275 patent is invalid. *See Bausch & Lomb Inc. v. Alcon Labs., Inc.*, 914 F. Supp. 951, 952 (W.D.N.Y. 1996) ("If this Court finds that [the patent] is not invalid and that Alcon has infringed it, and orders Alcon to pay damages to B&L for such infringement, then Alcon would have no ability to recover those damages if at a later date the PTO determined that the . . . patent is invalid").

Moreover, a stay would also benefit plaintiffs because their potential liability for infringement of the '275 patent may be limited if the claims of the '275 patent are amended as a result of the reexamination or reissue process. Under the continuity doctrine, if an amended claim of a reissued or reexamined patent is not "substantially identical" to an original claim of that patent, then the patent holder cannot seek damages for any infringement of the amended claim that occurred before the date on which the patent

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emerged from reissue or reexamination. 35 U.S.C. § 252 ("the reissued patent, to the extent that its claims are substantially identical with the original patent, shall constitute a continuation thereof and have effect continuously from the date of the original patent."); 35 U.S.C. § 307 (applying 35 U.S.C. § 252 to reexamination proceedings). Accordingly, plaintiffs' infringement liability could be significantly reduced if the '275 patent substantially changes as a result of reissue or reexamination. *See Laitram Corp. v. NEC Corp.*, 163 F.3d 1342, 1346 (Fed. Cir. 1998) ("If substantive changes have been made to the original claims, the patentee is entitled to infringement damages only for the period following the issuance of the reexamination certificate.").

Finally, a stay of this litigation will result in expedited examination by the PTO—a tactical *benefit* to all parties. The Manual of Patent Examining Procedure provides that "reissue applications involved in 'stayed litigation' will be taken up for action in advance of other reissue applications. Great emphasis is placed on the expedited processing of such reissue applications." MPEP § 1442.03. The PTO also accelerates reexamination when the patent at issue is involved in stayed litigation. MPEP § 2263. Because reissue and reexamination proceedings will move forward regardless of whether this litigation is stayed, it is to the advantage of all parties to aid in expediting the PTO's evaluation of the patent at the center of these lawsuits.

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IV. CONCLUSION

To prevent duplicative litigation and potentially wasteful efforts by all parties and the Court, Columbia respectfully requests that this Court grant its motion to stay all proceedings in this multidistrict litigation pending the outcome of the reexamination of the '275 patent.

Respectfully submitted,

THE TRUSTEES OF COLUMBIA UNIVERSITY IN THE CITY OF NEW YORK

By its attorneys,

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